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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,709	01/28/2002	John C. Herr	9426-015	6148

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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,709	HERR ET AL.	
	Examiner	Art Unit	
	Samuel W. Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

Claims 1-30 are pending.

Applicants' preliminary amendment filed 11/24/03, which amends claims 1 and 7-11 has been entered.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-6 and 29-30, drawn to a polynucleotide, a vector comprising the polynucleotide and a host cell comprising said vector, a kit comprising nucleotide probe capable of hybridizing to said polynucleotide or/and amplification of said polynucleotide encoding FSP95 polypeptide, and a method of producing said FSP95 polypeptide comprising growing the host cell comprising the polynucleotide, are classified in class 536, subclass 23.1, and class 435, subclasses 69.1, 320.1, 455 and 471.

2. Claims 7-11 and 16-17, drawn to an isolated polypeptide encoded by the Group 1 polynucleotide, and a pharmaceutical composition comprising said polypeptide, are classified in class 530, subclasses 300 and 350, class 424, subclasses 278.1.

3. Claims 12-15, 17 and 30, drawn to an antibody binds to the polypeptide encoded by Group 1 polynucleotide, a pharmaceutical composition comprising said antibody, and a kit comprising said antibody, are classified in class 530, subclasses 388.1 and 389.1, and class 424, subclass 178.1.

4. Claim 18, drawn to a method of inhibiting fertilization in a subject comprising administering to the subject the pharmaceutical composition comprising the antibody, is classified in class 514, subclass 2, and class 530, subclass 387.1.

5. Claim 18, drawn to a method of inhibiting fertilization in a subject comprising administering to the subject the pharmaceutical composition comprising the polypeptide, is classified in class 514, subclass 2, and class 530, subclasses 350 and 300.

6. Claim 19, drawn to a method of modulating the activity of FSP95 comprising contacting the cell that expresses the FSP95 polypeptide with the antibody, is classified in class 514, subclass 2, and class 530, subclass 387.1.

7. Claim 19, drawn to a method of modulating the activity of FSP95 comprising contacting the cell that expresses the FSP95 polypeptide with the polypeptide, is classified in class 514, subclass 2, and class 530, subclasses 300 and 350.

8. Claim 20, drawn to a method of modulating the activity of FSP95 comprising contacting the cell that expresses the FSP95 polypeptide with a kinase, is classified in class 514, subclass 2, and class 435, subclass 17.

9. Claim 20, drawn to a method of modulating the activity of FSP95 comprising contacting the cell that expresses the FSP95 polypeptide with a phosphatase, is classified in class 514, subclass 2, and class 435, subclass 21.

10. Claim 21, drawn to a method of diagnosing or screening for the presence of developing a fertility-related disorder associated with the presence of antibodies immunoreactive to FSP95 polypeptide in a subject comprising detecting the presence of the antibodies in a sample which is obtained from serum of the subject thereof, is classified in class 514, subclass 2.

11. Claims 22-23, drawn to a method of identifying a modulatory compound of FSP95 polypeptide comprising contacting said polypeptide with a candidate

compound and measuring the activity of the FSP95 polypeptide, are classified in class 514, subclass 2, and class 435, subclass 70.1.

12. Claims 22-23, drawn to a method of identifying a modulatory compound of FSP95 polypeptide comprising contacting a cell expressing said polypeptide with a candidate compound and measuring the activity of the FSP95 polypeptide, are classified in class 514, subclass 2, and class 435, subclass 70.1.

13. Claim 24, drawn to a method of treating a subject suffering from a fertility-related disorder comprising administering the polynucleotide of Group 1 to the subject, is classified in class 514, subclass 44, and class 536, subclass 23.1.

14. Claim 25, drawn to a method of treating a subject suffering from a fertility-related disorder comprising administering the polypeptide of Group 2 to the subject, is classified in class 514, subclass 44, and class 530, subclasses 300 and 350.

15. Claim 26, drawn to a method of treating a subject suffering from a fertility-related disorder comprising administering the antibody of Group 3 to the subject, is classified in class 514, subclass 44, and class 530, subclass 387.1.

15. Claims 27-28, drawn to a transgenic non-human animal comprising a transgene encoding the Group 3 polypeptide, is classified in class 800, subclass 4, and class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1, 2 and 3 are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention 1 is drawn to polynucleotide, Invention 2 drawn to polypeptide while Invention 3 drawn to antibody. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because

each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

In addition, Invention 1 is directed to polynucleotides that is classified in class 536, subclass 23.1 whereas Invention 3 is directed to antibody that is classified in class 530, subclass 387.1. Thus, they acquire the different classification.

Invention 1 (polynucleotide) and Invention 3 (antibody) are distinct from each other because of the materially different structures of the compounds claimed. The nucleic acid is composed of deoxyribonucleotides linked by phosphodiester bonds and forms a double helix as a stable conformation that is a functionally structural characteristic. While antibody is composed of amino acid residues linked by peptide bond. Thus, biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Inventions 2 (polypeptide) and Invention 3 (antibody) are distinct from each other because of the materially different structures of the compounds claimed. Although antibody is belong to a types of polypeptide, antibody is glycosylated and its tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. Thus, the macromolecule of each invention would be expected to exhibit different physical and biochemical properties, and are capable of separate manufacture or use.

Inventions 1-3 are patentably distinct from the multicellular product (transgenic non-human animal) of Invention 16. The transgenic animal is living organism which function and biochemical properties are distinct from the composition/product of Inventions 1-3. The composition of each invention would be expected to exhibit different physical/physiological and chemical/biochemical properties, and are capable of separate manufacture or use.

Inventions 4-16 are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use

together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the Groups 4-16 are directed to different methods, e.g., the Group 4 method drawn to inhibiting fertilization in a subject comprising administering to the subject the pharmaceutical composition comprising the **antibody** whereas the Group 5 method is drawn to comprising administering to the subject the pharmaceutical composition comprising the **polypeptide**, i.e., the starting material and/or ingredient and technical consideration are distinct between the methods thereof.

Invention 1 is related to Inventions 6 and 13 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide can be used in hybridization assaying for polynucleotide interaction.

Invention 2 is related to Inventions 5, 7, 11 and 14 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be used in a proteinchip array to investigating signal transduction pathway, for example.

Invention 3 is related to Inventions 4, 10 and 15 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody can be used in an immunoreactions for investigating protein-protein and antigen-antibody interactions, for example.

Invention 1 is unrelated to Inventions 4-5, 7-12 and 14-16. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the outcome and mechanism of using polynucleotide (Invention II), e.g., in

hybridization reaction, or directing protein synthesis, is distinct or/and different from the results and mechanisms of using the polypeptide (e.g., the FSP95 polypeptide mediated treating a disorder state associated with the fertilization in Invention 5), and using antibody having specific immunological activity that the polynucleotide does not have.

Invention 2 is unrelated to Inventions 4, 6, 8-10, 12-13 and 15. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the outcome and physiological mechanism of using the polypeptide are distinct or/and different from the results and actions of using the antibody which has specific immunological activity that the polypeptide does not have, and using the polynucleotide which is capable of directing the protein synthesis which capability the polypeptide does not have.

Invention 3 is unrelated to Inventions 5-9 and 11-14 . Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the outcome and physiological mechanism of using the antibody are distinct or/and different from the results and actions of using the polypeptide and using the polynucleotide which both do have immuno-reactivity of the antibody thereof.

Additional Election Under 35 USC 121

Applicant is required under 35 US 121 (1) to elect a single disclosed polynucleotide or polypeptide or antibody to which claims are restricted; and (2) to list all claims readable thereon including those subsequently added.

If Group 1 is elected, applicant is required to elect one nucleotide sequence with identified SEQ ID NO:_ from claim 1 because polypeptide of SEQ ID NO:2 encoded by the Group 1 polynucleotide does not comprise the instant SEQ ID NO:5, 6 or 7, and there is no consensus or core sequence shared by the sequences SEQ ID NOs: 5-7.

If Group 2 is elected, applicant is required to elect one amino acid sequence with identified SEQ ID NO:_ from claims 7-11 for the reason mentioned above.

If Group 3 is elected, applicant is required to elect one antibody specifically binds to an amino acid sequence with identified SEQ ID NO:_ from claim 12 because the amino acid sequences of SEQ ID NOs: 1, 5, 6 and 7 are structurally distinct/different from one another (see the above statement).

If any one of Groups 4-7, 10-11 and 13-15 (directed to process claims) is elected, applicant is required to elect one antibody (from Group 4, 10 or 15), one polypeptide (from Group 5, 7, 11 or 14), or one polynucleotide (from Group 6 or 13) because of the reasons set forth above.

If Group 16 is elected, applicant is required to elect one polynucleotide (i.e., the "transgene" sequence) from claim 1 because of the reasons set forth above.

It should be noted that this additional election of the restriction requirement is not species election but rather the additional election under 35 US 121 since the above-mentioned nucleotide sequences are distinct/different from one another in structure and/or functions; e.g., nucleotide sequences encoding the SEQ ID NOs:2 and 5-7 are distinct/different from one another because the amino acid sequences of SEQ ID NOs: 5-7 do not have common core or consensus sequence or motif(s) and because the full-length FSP95 peptide sequence of SEQ ID NO:2 comprises none of SEQ ID NOs: 5, 6 or 7; i.e., the polynucleotide of SEQ ID NO:1 encoding said SEQ ID NO:2 does not contain the corresponding nucleotide sequence encoding SEQ ID NO:5, 6 or 7 thereof.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend**

from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Samuel W. Liu, Ph.D.
May 10, 2006

JON WEBER
SUPERVISORY PATENT EXAMINER